ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)

June 2001

BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	16172	15367	15506	0	0	0	0	0	0	0
808 DOD DRUG & VACC AD	5009	4592	4073	0	0	0	0	0	0	0
811 MIL HIV VAC&DRUG DEV	2597	5699	6341	0	0	0	0	0	0	0
836 COMBAT MEDICAL MATL AD	3893	4228	4200	0	0	0	0	0	0	0
837 SOLDIER SYS PROT-AD	855	848	892	0	0	0	0	0	0	0
853 COMBAT TRAUMA PATIENT SIMULATION	3818	0	0	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification:

PLEASE NOTE: This administration has not addressed FY2003-2007 requirements. All FY 2003-2007 budget estimates included in this book are notional only and subject to change.

This program element (PE) funds the advanced development (AD) of medical materiel necessary to field an effective capability for counteracting infectious diseases, treating, diagnosing and evacuating combat casualties, and developing operational medical drugs and materiels.

The PE funds AD of systems for medical protection against naturally occurring diseases and human immunodeficiency virus (HIV). These initiatives directly enhance military forces deployability and survivability through preventative protection against expected threats in areas of potential conflict around the globe. This includes development and initial human testing of vaccines, prophylactics, and therapeutic drugs.

Additionally, the PE supports AD of field medical equipment and drugs essential for combat casualty care on all battlefields and military operations other than war. Systems include resuscitators, blood substitutes, advanced sensors and diagnostic algorithms, field x-ray, field production of medical grade oxygen, intensive care delivery platforms and litters, and hemostatic dressing. These products have the potential to significantly enhance force sustainment (both physiologically and psychologically) by providing a more responsive, versatile, and empowered forward health care.

The PE also funds AD of systems that provide enhancement of or protection against physiological and psychological factors affecting cognitive and physical performance imposed by military systems, combat operations, or the environment. These efforts have direct relationships with soldier survivability and lethality through improved soldier mental and physical performance.

This program is managed by the U.S. Army Medical Research and Materiel Command. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

Core projects without R-2A Exhibits which contain less than $1M in FY 2002/2003 are described below:

Project 837, Soldier System Advanced Protection, supports demonstration and validation of preventive medicine materiel including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions.

This PE also includes Congressionally directed research on combat trauma patient simulation (project 853) and low-power blood cooling and storage

devices.

B. Program Change Summary	FY 2000	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2001 PB)	16566	12235	14669	0
Appropriated Value	16723	15509	0	
Adjustments to Appropriated Value	0	0	0	
a. Congressional General Reductions	0	0	0	
b. SBIR / STTR	-394	0	0	
c. Omnibus or Other Above Threshold Adjustments	-60	0	0	
d. Below Threshold Reprogramming	0	0	0	
e. Rescissions	-97	-142	0	
Adjustments to Budget Years Since FY2001 PB	0		837	
Current Budget Submit (FY 2002/2003 PB)	16172	15367	15506	0

Change Summary Explanation: Funding - FY 2003: Funds were realigned to support Hemostatic Dressing clinical trials (+4940).

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - DEM/VAL	**0603807A - Medical Systems Advanced Development**	**808**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
808 DOD DRUG & VACC AD	5009	4592	4073	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This project funds program definition and risk reduction of candidate medical countermeasures such as vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing in volunteers against naturally occurring infectious diseases of mission-degrading or mission-aborting potential, thereby improving deployability and survivability of forces. Work performed in laboratories and among troop populations is directed to prevent, diagnose, and treat viral, bacterial, and parasitic disease to prevent casualties, sustain operational performance, and minimize deaths and disability of armed forces during military operations. Preclinical trials, as well as phase 1, 2, and 3 trials, are performed as required for drug, vaccine, and device licensure by the U.S. Food and Drug Administration (FDA). Major advanced development contractors include Southern Research Institute, Birmingham AL; South Florida Research Institute, Miami, FL; Institute of Biology for the Army, Rio de Janeiro, Brazil; and Kenya Medical Research Institute, Nairobi, Kenya. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1909 Conducted studies and reviews of malarial/antimalarial vaccines, drugs, and diagnostics:
  - Conducted phase 1 study to refine dose regimen for RTS,S malaria vaccine.
  - Conducted preclinical carcinogenicity study and Milestone (MS) II In-Process Review (IPR) for Tafenoquine antimalarial drug.
  - Conducted MS I IPR and transitioned rapid detection of Plasmodium-infected mosquitoes program to the Program Definition and Risk Reduction (PDRR) phase.
  - Conducted MS I IPR and transitioned malaria rapid diagnostic device program to the Program Definition and Risk Reduction (PDRR) phase.
- 363 Continued phase 1/2 safety and efficacy field trials for the Shigella flexneri diarrheal vaccine in Bangladesh; chosen for the high endemic occurrence of this disease and suitable medical infrastructure.
- 1027 Conducted or completed trials and evaluations of grouped infectious disease vaccines and drugs (Hepatitis E and Leishmania):
  - Completed phase 1b and started phase 2 clinical trials in Nepal, an area of high endemicity, for the Hepatitis E vaccine program.

FY 2000 Accomplishments (Continued)

- 1395 Conducted a MS I IPR, started development of a human challenge model for clinical evaluation of efficacy, began sequencing and cloning of dengue types 2, 3, and 4 components, and conducted phase 1b clinical trials to select dose formulations for the dengue tetravalent Flavivirus vaccine.

- 315 Conducted appropriate reviews and transitioned Insect Vector Control products:
  - Conducted MS I IPR and transitioned lethal ovitrap for dengue vectors program to the PDRR phase.
  - Conducted a MS I IPR and transitioned camouflage face paint with insect repellent and reduced infrared signature program to the PDRR phase.

Total 5009

FY 2001 Planned Program

- 1025 Complete and/or continue studies, and conduct reviews of malarial/antimalarial vaccines, drugs, and diagnostics:
  - Complete phase 1 study to refine dose regimen for RTS,S malaria vaccine.
  - Continue developmental testing of prototype kit for the rapid detection of Plasmodium-infected mosquitoes.
  - Conduct developmental testing of prototype malaria rapid diagnostic device.
  - Conduct a MS I IPR and transition program (artelinic acid) for the treatment of severe and complicated malaria to the PDRR phase.
- 694 Conduct trials and reviews of diarrheals:
  - Conduct expanded phase 2 safety and efficacy field trial for Shigella flexneri vaccine in Bangladesh; chosen for the high endemic occurrence of this disease and suitable medical infrastructure.
  - Conduct a MS I IPR and transition Shigella sonnei vaccine program to the PDRR phase.
- 1129 Conduct evaluations and trials of grouped infectious disease vaccines and drugs (Hepatitis E, Leishmania, and Japanese Encephalitis):
  - Conduct a phase 2 clinical trial in Nepal, an area of high endemicity, to evaluate the effectiveness of the Hepatitis E vaccine.
  - Conduct potency evaluation of Leishmania skin test components for the diagnosis of Leishmania infections and conduct phase 1 safety study.
  - Reformulate paromomycin/gentamicin topical antileishmanial cream for future evaluation in clinical trials.
  - Conduct a MS I IPR and transition the Japanese encephalitis vaccine (improved) program to the PDRR phase.

FY 2001 Planned Program (Continued)

- 1056 Conduct or complete evaluations of Flavivirus vaccines:
  - Complete development of human challenge model for the clinical evaluation of the efficacy of dengue tetravalent vaccines.
  - Complete sequencing and cloning of dengue types 2, 3, and 4 for use in evaluation of infectious clone vaccines.
  - Conduct preclinical effectiveness evaluation of a prototype infectious clone dengue vaccine and conduct phase 1 safety evaluation.
- 579 Conduct or continue appropriate testing and review of insect vector control products:
  - Continue developmental testing of a prototype lethal ovitrap for dengue vectors.
  - Conduct developmental testing of camouflage face paint with insect repellent and reduced infrared signature.
- 109 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 4592

FY 2002 Planned Program

- 1232 Conduct trials, testing, and reviews of malarial/antimalarial vaccines, drugs, and diagnostics:
  - Conduct phase 2 clinical trial of new dose regimen of RTS,S malaria vaccine.
  - Continue developmental testing of prototype kit for the rapid detection of Plasmodium-infected mosquitoes.
  - Conduct MS II IPR for the malaria rapid diagnostic device program.
  - Conduct preclinical safety evaluation of artelinic acid for the treatment of severe and complicated malaria.
- 410 Conduct and/or complete clinical trials, evaluations, and reviews of diarrheal vaccines:
  - Complete expanded phase 2 safety and efficacy field trial for Shigella flexneri vaccine in Bangladesh and conduct MS II IPR.
  - Conduct phase 1 clinical safety evaluation of Shigella sonnei vaccine for the prevention of traveler's diarrhea.
  - Conduct a MS I IPR for the Shigella dysenteriae vaccine program.
- 1288 Conduct trials and reviews for grouped infectious disease vaccines and drugs (Hepatitis E, Leishmania, and Japanese Encephalitis):
  - Complete a phase 2 clinical trial in Nepal to evaluate the effectiveness of the Hepatitis E vaccine and conduct MS II IPR.
  - Conduct an MS II IPR for the Leishmania skin test program.

FY 2002 Planned Program (Continued)

- Conduct phase 2 clinical trial of new formulation of paromomycin/gentamicin topical antileishmanial cream and conduct MS II IPR.
- Conduct an MS I IPR for the Group B Meningitis vaccine program.
- Conduct phase 1 clinical safety evaluation of the improved Japanese encephalitis vaccine.

• 760 Complete phase 1 safety evaluation of a prototype infectious clone dengue Flavivirus vaccine.

• 383 Proceed with developmental testing and evaluation of insect vector control products:

- Continue developmental testing of a prototype lethal ovitrap for dengue vectors.
- Complete developmental testing of camouflage face paint with insect repellent and reduced infrared signature and conduct MS II IPR.

Total 4073

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure.

D. Schedule Profile	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Tafenoquine antimalarial (MSII)	4Q			0	0	0	0	0
Leishmania Skin Test (MSII)			1Q	0	0	0	0	0
Shigella flexneri (MSII)			2Q	0	0	0	0	0
Paromomycin/Gentamicin (MSII)			3Q	0	0	0	0	0
Hepatitis E vaccine (MSII)			4Q	0	0	0	0	0
RTS,S malaria vaccine (MSII)				0	0	0	0	0
Malaria Rapid Diagnostic Device (MSI); (MSII)	1Q		1Q	0	0	0	0	0
Camouflage face paint (MSI); (MSII)	1Q		4Q	0	0	0	0	0
Dengue tetravalent vaccine (MSI); (MSII)	3Q			0	0	0	0	0
Lethal ovitrap for dengue-infected mosquitoes (MSI); (MSII/III)	4Q			0	0	0	0	0

D. Schedule Profile (continued)	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Detection of Plasmodium-infected mosquitoes (MSI); (MSII/III)	4Q			0	0	0	0	0
Artelinic acid (MSI); (MSII)		3Q		0	0	0	0	0
Shigella sonnei vaccine (MSI); (MSII)		3Q		0	0	0	0	0
Japanese encephalitis vaccine (improved) (MSI); (MSII)		4Q		0	0	0	0	0
Group B meningitis vaccine (MSI); (MSII)			3Q	0	0	0	0	0
Shigella dysenteriae vaccine (MSI); (MSII)			3Q	0	0	0	0	0
Hantavirus vaccine (MSI)				0	0	0	0	0
New standard military insect repellent (MSI)				0	0	0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

June 2001

BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
808

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			1244	1118		987		0	0	0	0	0
Subtotal:			1244	1118		987		0		0	0	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			236	121		106		0	0	0	0	0
Subtotal:			236	121		106		0		0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

June 2001

BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
808

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			4393	2888		2570		0	0	0	0	0
Subtotal:			4393	2888		2570		0		0	0	0

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			995	465		410		0	0	0	0	0
Subtotal:			995	465		410		0		0	0	0
Project Total Cost:			6868	4592		4073		0		0	0	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - DEM/VAL	**0603807A - Medical Systems Advanced Development**	**811**

COST (In Thousands)		FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
811	MIL HIV VAC&DRUG DEV	2597	5699	6341	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) research for demonstration and validation of candidate vaccines and drugs through safety, immunogenicity, and small-scale efficacy testing and behavioral intervention in volunteers. Preclinical trials, as well as phase 1, 2, and 3 trials, are performed as required for drug, vaccine, and device licensure by the U.S. Food and Drug Administration (FDA). Development efforts are directed to answer militarily unique needs affecting manning, mobilization, and deployment. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 50 Redesigned and refocused the HIV vaccine development program to follow a prime-boost vaccination strategy (clade E - a strain prevalent in developing countries). Conducted a Milestone (MS) 0/I In-Process Review (IPR) on prime-boost HIV vaccine strategy (clade E).
- 604 Conducted phase 1 clinical trials to select optimal dose levels of boost component of HIV vaccines (clade E).
- 1943 Selected prime HIV vaccine candidate. Planned and began multi-year phase 2 clinical trials to down-select among three boost HIV vaccine component candidates (clade E).

Total 2597

FY 2001 Planned Program

- 50 Complete phase 1 clinical trials to select optimal dose levels of boost component of HIV vaccines (clade E).
- 2422 Continue multi-year phase 2 clinical trials to down-select among three boost HIV vaccine component candidates (clade E).
- 3057 Conduct field site development. Conduct studies to identify potential subject populations for involvement in phase 3 pivotal clinical trial of prime-boost HIV vaccine (clade E).
- 170 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.

Total 5699

FY 2002 Planned Program

- 609 Complete multi-year phase 2 clinical trials to down-select among three HIV vaccine boost candidates (clade E).
- 2519 Conduct field site development to determine best location for vaccine trials in area with high HIV rate. Conduct studies to identify potential subject populations for involvement in phase 3 pivotal clinical trial of a prime-boost HIV vaccine (clade E).
- 50 Select boost component of HIV vaccine candidate. Conduct MS II IPR on prime-boost HIV vaccine (clade E).
- 3163 Plan and begin multi-year phase 3 clinical trial to determine effectiveness of prime-boost HIV vaccine (clade E).

Total 6341

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Test and evaluate commercially developed vaccine candidates in government-managed trials.

D. Schedule Profile	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
HIV Vaccine (MS I); (MS II)	4Q		1Q	0	0	0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

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BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
811

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	3698	765		846		0	0	0	0	0
Subtotal:			3698	765		846		0		0	0	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			157	339		372		0	0	0	0	0
Subtotal:			157	339		372		0		0	0	0

Remarks: Not Applicable

ARMY RDT&E COST ANALYSIS(R-3)

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BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
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III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	2037	4497		5016		0	0	0	0	0
Subtotal:			2037	4497		5016		0		0	0	0

Remarks: Not Applicable

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually.			45	98		107		0	0	0	0	0
Subtotal:			45	98		107		0		0	0	0

Remarks: Not Applicable

Project Total Cost:			5937	5699		6341		0		0	0	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

June 2001

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT
4 - DEM/VAL	**0603807A - Medical Systems Advanced Development**	**836**

COST (In Thousands)	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	Cost to Complete	Total Cost
836 COMBAT MEDICAL MATL AD	3893	4228	4200	0	0	0	0	0	0	0

A. Mission Description and Budget Item Justification: The project supports advanced development of new and improved systems essential for battlefield casualty care, patient transport and evacuation, and return to duty in support of special contingency and conventional force operations. These systems decrease mortality rates and enhance force sustainment by providing more responsive, versatile, and deployable forward health care. Advanced development contractors/universities include United Defense Limited Partnership; Mission Medical; IGR Enterprises, Inc; and PM Bradley Fighting Vehicle Systems and Naval Research Center. This program supports the Legacy to Objective transition path of the Transformation Campaign Plan (TCP).

FY 2000 Accomplishments

- 1884 Conducted Force Development Experiment for the Armored Medical Evacuation Vehicle (AMEV). Completed the Engineering and Manufacturing Development vehicle for production qualification testing.
- 1018 Conducted series of four diverse animal model evaluations on nine candidate hemostatic dressings leading to a Milestone (MS) I In-process Review (IPR) and down-selection of products for further development.
- 665 Continued to improve field medical treatment and treatment aid devices.

  - Conducted development user tests for the Thawed Blood Processing System (TBPS), culminating in a MS I/II IPR for TBPS.

  - Completed user testing of Special Operations Resuscitation and Surgical Station for far-forward resuscitation and stabilization. Completed the Technical Data Package.

  - Built prototype Ceramic Oxygen Generator System modules that incorporate key technologies for a portable oxygen generator to replace oxygen bottles used far-forward.
- 326 Collaborated with the Soldier Biological and Chemical Command to incorporate Warrior Medic design requirements into the completely revised and rebaselined Land Warrior program.

Total 3893

FY 2001 Planned Program

•	187	Prepare for testing and evaluation of medical evacuation systems.
		- Start Interim Armored Vehicle (a component of the Interim Brigade Combat Team (IBCT)) modification for medical capability, conduct MS I (if necessary), and participate in the Force Development Exercises.
		- Complete initial operational test and evaluation for Critical Care System for Trauma and Transport (CSTAT) and conduct MS I/II.
•	1922	Secure commercial partners for hemostatic dressing development. Begin safety and efficacy trials in animals for hemostatic dressing using Good Laboratory Practice.
•	1498	Conduct transitions and product evaluation of field medical treatment and treatment aid devices.
		- Start operational tests and develop disposable filtration cassette for TBPS.
		- Integrate prototype modules into a rugged, lightweight portable Ceramic Oxygen Generator System to demonstrate battlefield capabilities.
		- Evaluate four candidate products for a one-handed tourniquet.
		- Conduct a MS 0 for Dental Field Treatment and Operating System and start reliability tests.
•	527	Prepare and conduct tests and investigations for medical monitoring and imaging systems.
		- Prepare for initial operational test and evaluation for Warrior Medic program.
		- Start and complete market investigation for the Filmless Digital Imaging System.
		- Begin development of an analysis of alternatives for the Non-Contact Heart Rate Monitor.
•	94	Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs.
Total	4228	

FY 2002 Planned Program

•	635	Demonstrate and evaluate medical evacuation systems.
		- Evaluate and begin necessary modifications to the Interim Armored Vehicle.
		- Begin evaluation of preplanned product improvements for second version CSTAT in order to meet Operational Requirements Document (ORD) requirements.
		- Conduct a Market Investigation for the mini-STAT (a small lightweight system for transporting trauma patients).
•	2147	Start human clinical trials for hemostatic dressing for elective surgery indication.
•	1091	Conduct testing and milestone IPRs for field medical treatment and treatment aid devices.
		- Complete FDA clinical trials of the TBPS, and conduct MS III.
		- Perform Ceramic Oxygen Generator System user testing, and conduct a MS I IPR.
		- Conduct down-select to single one-handed tourniquet design and conduct MS I/II.
		- Begin reliability/survivability tests for the Dental Field Treatment and Operating System and conduct MS I.
•	327	Conduct tests and investigations for medical monitoring and imaging systems.
		- Conduct an initial operational test and evaluation for the Warrior Medic System and prepare for a MS II/III.
		- Develop an analysis of alternatives for the Non-Contact Heart Rate Monitor.
Total	4200	

B. Other Program Funding Summary: Not applicable for this item.

C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed tests for hardening or other modification.

D. Schedule Profile	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
Warrior Medic (MSII/III)				0	0	0	0	0
Hemostatic Foam (MSI)				0	0	0	0	0
Hemostatic Dressing (MSI); (MSII); (MSIII)	4Q			0	0	0	0	0
Non-Contact Heart Rate Monitor (MSI)				0	0	0	0	0
Ceramic Oxygen Generator System (MSI); (MSII/III)			4Q	0	0	0	0	0
Thawed Blood Processing System (MSI/II); (MSIII)	4Q		4Q	0	0	0	0	0
Interim Armored Vehicle (MSI); (MSII)		4Q		0	0	0	0	0
Critical Care System for Trauma and Transport (MSI/II); (MSIII)		3Q	4Q	0	0	0	0	0
Dental Field Treatment and Operating System (MSI); (MSII/III)			3Q	0	0	0	0	0
One Handed Tourniquet (MSI/II)			3Q	0	0	0	0	0

ARMY RDT&E COST ANALYSIS(R-3)

June 2001

BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
836

I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . AMEV		PM Bradley, Warren, MI	4655	0		0		0	0	0	0	0
b . No other contract exceeds $1M			0	0		0		0	0	0	0	0
Subtotal:			4655	0		0		0		0	0	0

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:			0	0		0		0		0	0	0

Remarks: No product/contract costs greater than $1M individually.

ARMY RDT&E COST ANALYSIS(R-3)

June 2001

BUDGET ACTIVITY
4 - DEM/VAL

PE NUMBER AND TITLE
0603807A - Medical Systems Advanced Development

PROJECT
836

III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:			0	0		0		0		0	0	0

Remarks: No product/contract costs greater than $1M individually.

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2001 Cost	FY 2001 Award Date	FY 2002 Cost	FY 2002 Award Date	FY 2003 Cost	FY 2003 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than $1M individually			6326	4228		4200		0	0	0	0	0
Subtotal:			6326	4228		4200		0		0	0	0
Project Total Cost:			10981	4228		4200		0		0	0	0